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PTO/SB/05 (2/98)

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**UTILITY
PATENT APPLICATION
TRANSMITTAL**

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No. _____

First Inventor or Application Identifier William M. Yarbrough

Title Urushiol Induced Contact Dermatitis Treatment

Express Mail Label No. EF-762591868US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. Fee Transmittal Form (e.g. PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. Specification [Total Pages 14]
(preferred arrangement set forth below)
 - Descriptive title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed.-sponsored R&D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. Drawing(s) (35 U.S.C. 113) [Total Sheets _____]
4. Oath or Declaration [Total Pages 3]
 - a. Newly executed (original or copy)
 - b. Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 17 completed)
[Note Box 5 below]
 - c. DELETION OF INVENTOR(S)
Signed statement attached deleting
inventor(s) named in the prior application,
see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).
5. Incorporation By Reference (useable if Box 4b is checked)
The entire disclosure of the prior application, from which a
copy of the oath or declaration is supplied under Box 4b, is
considered to be part of the disclosure of the accompanying
application and is hereby incorporated by reference therein.

17. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:

Continuation Divisional Continuation-in-part (CIP) of prior application No: _____ / _____

Prior application information: Examiner _____

Group / Art Unit _____

18. CORRESPONDENCE ADDRESS

<input type="checkbox"/> Customer Number or Bar Code Label (Insert Customer No. or Attach bar code label here):	or <input checked="" type="checkbox"/> Correspondence address below				
Name KNECHTEL, DEMEUR & SAMLAN					
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Name (Print/Type) Robert L. Knechtel	Registration No. (Attorney/Agent) 36,845
Signature 	Date 7/3/99

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Docket No. _____

VERIFIED STATEMENT (DECLARATION)
CLAIMING SMALL ENTITY STATUS (37 C.F.R. 1.9(F) AND
1.27 (D) SMALL BUSINESS CONCERN

I hereby declare that I am:

The owner of a small business concern identified below;

An official of a small business concern empowered to act on behalf of the concern identified below:

Name of concern: The William M. Yarbrough Foundation

Address of concern: 509 West Altorfer Lane
Peoria, IL 61615

I hereby declare that the above-identified small business concern qualifies as a small business concern as identified in 13 C.F.R. 121.3-18, and reproduced in 36 C.F.R. 1.9(D), for purposes of paying reduced fees under Sections 41(1) and (b) of Title 35, United States Code, in the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on full time, part time, or temporary basis during each of the date periods of the fiscal year, and (2) concerns or affiliates of each other when one concern, directly or indirectly, either controls or has power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that the rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled

"URUSHIOL INDUCED CONTACT DERMATITIS TREATMENT"

By inventor(s): William M. Yarbrough

Described in:

- The specification filed herewith;
- Application serial number _____, issued _____.
- Patent number _____, issued _____.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. 1.9(D) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(D) or a non-profit organization under 37 C.F.R. 1.9(E).

Name: The William M. Yarbrough Foundation

- Individual
- Small business concern
- Non-profit organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate [37 C.F.R. 1.28(B)].

I hereby declare that all statements made herein of my own knowledge are true and that all

statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of person signing: William M. Yarbrough

Title of person other than owner: William M. Yarbrough (PRESIDENT)

Residence and Post Office Address of person signing:

509 West Altorfer Lane
Peoria, IL 61615

Signature: William M. Yarbrough

Dated: 5-1-99

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PATENT

Express Mail Number: EE762591868US

UNITED STATES DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INVENTION: Urushiol Induced Contact Dermatitis Treatment and Method of Use
INVENTORS: William M. Yarbrough
Corey Schroeter

1

I. FIELD OF THE INVENTION

2

The present invention relates to treatments for allergic dermatitis and, more particularly, to a treatment for Toxicodendron dermatitis, which results from contact with the Rhus oleoresin urushiol.

5

II. BACKGROUND OF THE INVENTION AND PRIOR ART

6

Urushiol is the toxin responsible for the allergic dermatitis caused by contact with the sap of commonly encountered noxious plants such as poison ivy, poison oak, and poison sumac, and related plants found throughout the world. Urushiol or related chemicals are also found in the Anacardiaceae group, which includes, among others, the lacquer tree of Asia, mango tree, cashew shell oil and in certain nut shells, such as the walnut.

12

The American Academy of Dermatology estimates that there are up to 50 million cases of urushiol induced contact dermatitis annually in the United States alone. No one is sure of the number of world wide annual exposures but some experts estimate that the number could be double that of the United States. Accordingly, urushiol induced contact dermatitis is a world wide problem.

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Corey Schroeter

1 Chemically, urushiols are mixtures of catechols with long, hydrophobic,
2 carbon(alkyl) side chains at the three position of the catechol ring. For example, poison
3 ivy contains predominantly 3-*n*-pentadecylcatechols (C-15) and poison oak contains
4 predominantly 3-*n*- heptaecylcatechols (C-17). When located inside an unruptured plant
5 leaf, Urushiol is a light, colorless oil. When exposed to oxygen, urushiol easily oxidizes
6 and, after polymerizing, turns a blackish color.

7 The reaction is the result of exposure to the oleoresin containing the urushiol. The
8 reaction is an allergic eczematous contact dermatitis characterized by redness, swelling,
9 papules, vesicles, bullae, and streaking.

10 Treatment has historically consisted of attempting to remove the oil as quickly
11 after exposure as possible: applying rubbing alcohol, washing affected areas with water,
12 and showering with soap and water. Unfortunately, if the above procedure is not
13 commence within minutes of exposure the regimen will not remove the toxin but may limit
14 its spread.

15 Attempts have been made to find both prophylactic treatments as well as post-
16 exposure treatments. To date, no vaccine has been developed and the prior art treatments
17 are not without shortcomings. One treatment example is seen in U.S. Patent number
18 5,686,074 to Stewart which teaches and claims a treatment for poison ivy which includes a
19 composition including linseed oil, an astringent, a starch, an essential oil and a citrus oil.

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1 One shortcoming of this patent is that linseed oil can cause irritation itself. A second
2 shortcoming of this patent is that it requires that the composition be applied to the affected
3 areas up to twice a day until the rash is gone. The composition provides what appears to
4 be only very temporary palliative relief of poison ivy symptoms and does not appear to
5 alter the course of the malady.

6 Other proposed treatments are seen in U. S. Patent numbers 5,620,527, 5,011,689
7 4,499,086, 4,259,318, 4,002,737, 3,862,331, 3,875,301, and 3,922,342.

8 Yet other prior art attempts have focused on prophylactics for preventing the
9 dermatitis. One example is seen is U.S. Patent number 4,663,151 to Waali which
10 discloses and claims a prophylactic treatment based upon Aluminum Chlorhydrate. Of
11 course, the most significant shortcoming associated with prophylactic treatments is that
12 they are only effective if applied before exposure to the urushiol; an occurrence that rarely
13 takes place.

14 A significant advance in the treatment of poison ivy is seen in an unpatented
15 product sold under the mark Tech-Nu ® and manufactured by Tec Laboratories, Inc. of
16 Albany, Oregon. However, this product is not without shortcomings. This product was
17 originally developed as a treatment for radiation exposure. It was discovered, however,
18 that the product also provided some relief for poison ivy exposure. The main active
19 ingredient in the Tech-nu ® product is Octylphenoxy-polyethoxyethanol. The four octyl

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1 groups of this chemical are to large too surround the non polar moieties in the urushiol.
2 Therefore, it only partially matches the polarity of urushiol. Thus, the action of this
3 product renders the urushiol only partially inactive. Since the urushiol remains partially
4 active and continues to cause irritation, only temporary relief is provided and multiple
5 applications are necessary. Also, the chemical makeup of the product requires that it be
6 applied no later than eight hours after exposure to urushiol.

7 There is need, therefore, for a safe, effective treatment for dermatitis caused by
8 exposure to the toxin urushiol. The treatment should provide complete relief from the
9 signs and symptoms associated with the dermatitis in limited treatments and be effective at
10 any point during the dermatitis cycle.

11 **II. OBJECTS OF THE INVENTION**

12 It is an object of the present invention to provide a treatment for urushiol induced
13 allergic dermatitis, the treatment providing almost immediate and permanent relief in
14 usually one treatment.

15 It is a further object of the present invention to provide such a treatment in a
16 method that utilizes a composition that chemically attaches to available urushiol receptors
17 to block its allergic reaction properties and to release the urushiol so that it can be
18 removed from the skin.

19 It is yet another object of the present invention to provide a treatment for urushiol

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1 induced contact dermatitis that includes a first nonyl phenyl ethoxylate, a second nonyl
2 phenyl ethoxylate, acetylated lanolin alcohol, sodium lauroyl sarcominate, EDTA, a foam
3 stabilizer, water, and inert polyethylene granules.

4 It is a yet further object of the present invention to provide a treatment which is
5 safe to use.

6 It is yet another object of the present invention to provide a treatment for urushiol
7 induced allergic dermatitis which is topical, can be purchased over the counter and is
8 economical.

IV. SUMMARY OF THE INVENTION

10 The above objects of the invention are provided for in a topical treatment for
11 urushiol induced contact dermatitis. According to the invention, a method is provided for
12 applying a composition of substances to the effected area, working the composition into
13 the effected area, and removing the composition from the effected area. The composition
14 comprises at least one ethoxylate in combination with Sodium Lauroyl Sarconinate (or
15 "SLS"). It is believed that this combination binds to the available urushiol receptors
16 rendering it inactive. The affinity of the receptors for the ethoxylates also appears to
17 cause a release of the urushiol from its epidermal bonds for bonding to the composition.
18 An inert scrubbing agent, such as polyethylene beads, can also be included to assist in the
19 release of the urushiol. Acetylated lanolin alcohol, sodium lauroyl sarcominate, EDTA, a

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1 foam stabilizer, and water can also be added to the composition without effecting
2 performance.

3 **V. DETAILED DESCRIPTION OF THE INVENTION**

4 As noted above, urushiol is the toxin responsible for the contact dermatitis caused
5 by poison ivy, poison oak, and other urushiol containing plants. When housed inside an
6 unruptured plant leaf, urushiol is a light, colorless oil. The leaves are easily damaged by
7 the slightest contact or even breeze. Therefore, it is rare to find a plant that does not
8 have at least some ruptured leaves. When exposed to oxygen, urushiol easily oxidizes
9 and, after polymerizing, turns a blackish color.

10 The reaction experienced by most people is the result of exposure to the oleoresin
11 containing the urushiol. The reaction is an allergic eczematous contact dermatitis
12 characterized by redness, swelling, papules, vesicles, bullae, and streaking. Urushiol is the
13 name given to a family catechols having long, hydrophobic, carbon(alkyl) side chains at
14 the three position of the catechol ring. The chemical structure of the urushiol found in the
15 poison ivy plant is:

16

17 OH

18 OH

19 $(CH_2)_7CH_2CH(CH_2)_5CH_2$

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INVENTORS: William Yarbrough
Corey Schroeter

1 t is seen that the urushiol of the poison ivy plant contains predominantly 3-*n*-
2 pentadecacylcatechols (C-15). Poison oak is known to contain predominantly 3-*n*-
3 heptaacylcatechols (C-17). Other urushiol containing plants contain catechols that have
4 side chains of varying lengths.

5 It has been discovered that a hand scrub product manufactured and sold by the
6 Redman Scientific, Company of Dallas, Texas can alleviate the signs and symptoms of
7 urushiol induced contact dermatitis. The product has been sold for approximately twenty
8 years, and is known to be a safe, gentle hypoallergenic product. The product has been
9 sold as an industrial hand cleaner and has never heretofore been known to be effective
10 against urushiol toxicity. It has only been promoted as a hand cleaner.

11 Chemical analysis and research by the inventors has revealed that two of the
12 component parts of the Redman product are central to its effectiveness as a treatment for
13 urushiol induced contact dermatitis: an ethoxylate and Sodium Lauroyl Sarconinate. The
14 ethoxylate is a nonylphenol ethoxylate. Unlike the ethoxylate of the Tech-Nu ® product,
15 the present invention's ethoxylate has the large octyl groups removed. In this way, the
16 ethoxylate can "wrap" around the non-polar molecules of the urushiol. Further, the long
17 chain moiety of the present invention's ethoxylate is only four carbons long, as opposed to
18 ten. This feature also assists the ethoxylate in bonding to the urushiol more effectively.

19 However, the ethoxylate itself is not capable of forming a complete micelle around

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1 the urushiol. The inventors have discovered that the addition of Sodium Lauroyl
2 Sarcosinide, the micelle is completed and the urushiol can be cleansed away from the skin.
3 SLS also has a long carbon chain that can surround the non-polar portions of the urushiol.
4 In addition, SLS contains a highly polar end that aids in surrounding the polar ends of
5 urushiol and also in the invention's reactivity with water.

6 Thus, the combination of the ethoxylate and SLS create a large molecule that
7 contains flexible non-polar groups and soluble polar groups. This permits the inventive
8 composition to quickly and effectively surround the urushiol and then be rinsed away with
9 water, a highly polar substance.

10 The inventors have also discovered that the addition of an inert scrubbing agent
11 improves the action of the inventive composition. The scrubbing agent assists by causing
12 the urushiol to detach from the skin and place it in position for bonding with the active
13 chemical components of the inventive composition. Any inert agent will suffice but the
14 inventors believe that poly ethylene beads work best. The beads should be large enough
15 to be effective but not so large as to cause abrasions. The inventors suggest beads in the
16 range of 5 to 50 microns with an average size being approximately 25 microns or 50 mesh.

17 To make the inventive composition, an exact ratio of ethoxylate to SLS is not
18 critical. The only requirement is that the ethoxylate is completely reacted with the SLS,
19 creating a polymer. This will vary with the ethoxylate used, but the inventors have

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1 determined that a ratio of ethoxylate-to- SLS of 1.5:2 is preferred. The amount by weight
2 of polyethylene beads can vary according to the grittiness desired. The inventors have
3 found that a formula of ethoxylate:SLS:polyethylene of 40:20:40 is preferred but that
4 formulas of other concentrations are useful. Thus, for production purposes, formulas
5 having SLS ranging from 10 to 20 % by weight, ethoxylate ranging from 20 to 40 % by
6 weight, and polyethylene beads from 20 to 50% by weight are reasonable. But again, the
7 formula is not restricted to these ranges, which ranges are presented for example purposes
8 only.

9 Also, a cutting agent that does not chemically react with the composition may be
10 added. The cutting agent makes the overall composition flow more easily, thereby
11 enabling more packaging options such as tubes. The cutting agent must be added only in
12 sufficient amount that it promotes flow but does not effect the action of the composition.

13 In use, the composition is applied to an effected area and worked over the area by
14 a scrubbing motion. After sufficient time has elapsed to ensure that the effected area has
15 been adequately exposed to the composition, the composition and bound urushiol are
16 washed away. Experiments have demonstrated that a majority of people need only one
17 treatment to be relieved of itching; however, severe cases may require two treatments
18 approximately eight hours apart. The inventive composition works at varying rates of
19 effectiveness at any time during the rash cycle.

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INVENTORS: William Yarbrough
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CLAIMS

WE CLAIM:

- 1 1. A treatment for urushiol induced contact dermatitis comprising sodium lauroyl _____
- 2 sarcominate and a nonyl phenyl ethoxylate in combination.

- 1 2. The treatment for urushiol induced contact dermatitis of Claim 1 further including _____
- 2 a second nonyl phenyl ethoxylate.

- 1 3. The treatment for urushiol induced contact dermatitis of Claim 1 further including _____
- 2 acetylated lanolin alcohol.

- 1 4. The treatment for urushiol induced contact dermatitis of Claim 1 further including _____
- 2 polyethylene granules.

- 1 5. The treatment for urushiol induced contact dermatitis of Claim 1 further including _____
- 2 water.

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INVENTORS: William Yarbrough
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1 6. The treatment for urushiol induced contact dermatitis of Claim 1 further including
2 ethylenediaminetetraacetic acid.

1 7. The treatment for urushiol induced contact dermatitis of Claim 1 further including
2 a foam stabilizing agent.

1

1 8. The treatment for urushiol induced contact dermatitis of Claim 1 further including
2 a cutting agent.

1 9. The cutting agent of Claim 8 being selected from the group of aqueous based
2 solutions and oil based solutions.

1 10. A treatment for urushiol induced contact dermatitis comprising a nonyl phenyl
2 ethoxylate, sodium lauryl sarcominate, and scrubbing means.

1 11. The treatment of Claim 10 wherein the scrubbing mean is polyethylene beads.

1 12. The treatment for urushiol induced contact dermatitis of Claim 10 further including
2 a cutting agent.

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INVENTION: Urushiol Induced Contact Dermatitis Treatment

**INVENTORS: William Yarbrough
Corey Schroeter**

1 13. A treatment for urushiol induced contact dermatitis comprising:
2 a first nonyl phenyl ethoxylate, a second nonyl phenyl ethoxylate, acetylated lanolin
3 alcohol, sodium lauroyl sarcominate, EDTA, a foam stabilizer, water, and inert
4 polyethylene granules.

1 14. A treatment for urushiol induced contact dermatitis comprising a nonyl phenyl
2 ethoxylate, sodium lauroyl sarcominate, and EDTA.

1 15. A method for treating contact dermatitis comprising the steps of:
2 preparing a composition comprising a nonyl phenyl ethoxylate and sodium
3 lauroyl sarcominate;
4 applying the composition to an infected area;
5 permitting the composition to remain on the infected area a sufficient
6 amount of time to enable the composition of matter to cause an effect; and,
7 removing the composition from the effected area.

1 16. The method of Claim 15 wherein preparing the composition further includes
2 adding second nonyl phenyl ethoxylate.

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1 17. The method of Claim 15 wherein preparing the composition further includes
2 adding acetylated lanolin alcohol.

1 18. The method of Claim 15 wherein preparing the composition further includes
2 adding acetylated polyethylene granules.

1 19. The method of Claim 15 wherein preparing the composition further includes
2 adding water.

1 20. The method of Claim 11 wherein preparing the composition further includes
2 EDTA.

1 21. The method of Claim 11 wherein preparing the composition further includes a
2 foam stabilizer.

1 22. The method of Claim 15 further including the step of adding a thinning agent to
2 the composition.

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INVENTION: Urushiol Induced Contact Dermatitis Treatment
INVENTORS: William Yarbrough
Corey Schroeter

ABSTRACT

A treatment for urushiol induced contact dermatitis is provided for in a topical treatment. According to the invention, a method is provided for applying a composition substances to the effected area, working the composition into the effected area, and removing the composition from the effected area. The composition comprises at least one ethoxylate in combination with Sodium Lauroyl Sarconinate (or "SLS"). It is believed that this combination binds to the available urushiol receptors rendering it inactive. The affinity of the receptors for the ethoxylates also appears to cause a release of the urushiol from its epidermal bonds for bonding to the composition. An inert scrubbing agent, such as polyethylene beads, can also be included to assist in the release of the urushiol. Acetylated lanolin alcohol, sodium lauroyl sarcominate, EDTA, a foam stabilizer, and water can also be added to the composition without effecting performance.

A^ZANFEL APP

Docket No. _____

**DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **URUSHIOL INDUCED CONTACT DERMATITIS TREATMENT AND METHOD** the specification of which [x] is attached hereto, was filed on _____, as Application Serial No. _____ and was amended on _____ (if applicable).

I do not know and do not believe that this invention was ever used or known in the United States of America before my invention thereof, or patented or described in any printed publication in any country before my invention thereof, or more than one year prior to this application, that this invention was not in public use or on sale in the United States of America more than one year prior to this invention, that this invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on any application filed by me or my legal representatives, or assigned more than twelve months prior to this application, and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this Application by me or my legal representatives or assigns.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor certificate listed below and have also identified below any foreign application for patent or inventor certificate having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

Number _____

Country _____

Day/Month/Year Filed _____

Priority Claimed: Yes _____ No _____

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States Application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

Application serial No.: _____

Filing date: _____

Status: Patented, Pending, or Abandoned

And I hereby appoint Robert L. Knechtel, Registration No. 36,845, Alan B. Samlan, Registration No. 28,470, and Basil E. Demeur, Registration No. 23,049, of Knechtel, Demeur & Samlan, 30 South Wacker Drive, Suite 2810, Chicago, Illinois 60606, as my attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith.

It is requested that all communication be directed Robert L. Knechtel at the above address. All telephone calls should be made to (312) 655-9900.

I hereby declare all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: William M. Yarbrough

Inventor's signature: William M. Yarbrough

Citizenship: U. S.

Date: 5-1-99

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Full name of second inventor: Corey Schroeter

Inventor's signature: Corey Schroeter

Citizenship: U.S.

Date: 5-1-99

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EAST Peoria, IL 61611